## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION :

and GENEVANT SCIENCES GMBH, : CIVIL ACTION

Plaintiffs,

:

V.

: NO. 22-252

MODERNA, INC. and MODERNATX, INC.,

## <u>ORDER</u>

**AND NOW,** this 27<sup>th</sup> day of February, 2024, upon consideration of Plaintiffs' Discovery Dispute letters (D.I. 161, 184, 206) and Defendant's Responses (D.I. 183, 196, 212), and following a discovery hearing, it is hereby **ORDERED** that:

- 1. With respect to the timing of Defendant's production of samples,
  - a. Within **fourteen (14) days** from the date of this Order, Defendant shall produce to Plaintiffs all remaining information about batch/lot numbers;
  - b. Within **fourteen (14) days** from the date of this Order, Defendant shall produce all samples from the three lots/batches selected by Defendant; and
  - c. Within **twenty-one (21) days** from the date that Plaintiffs identifies the three lots/batches it has selected for sampling, Defendant shall produce all samples from those lots/batches.
- 2. With respect to Plaintiffs' request to preclude Defendant from making arguments about the applicability of test data generated by Plaintiffs for any lot based on its expiration date, that request is **denied as premature without prejudice** to Plaintiffs' right to re-raise this issue through motions *in limine*.
- 3. With respect to Plaintiffs' request for SM-102 LNP samples and related data,

- a. As to Plaintiffs' request for samples, counsel are instructed to meet and confer regarding Plaintiff's proposed compromise. If the parties are unable to reach an agreement, Plaintiffs may re-raise this issue with the Court; and
- b. As to certificates of analysis, Defendant shall complete production of all certificates of analysis showing SM-102 LNP lipid content. Plaintiffs must engage in a thorough review of the produced regulatory information, and, if they believe it is insufficient, Plaintiffs may re-raise this issue with the Court and establish how the need for the raw data underlying the certificates of analysis outweigh any undue burden on Defendants.
- 4. With respect to Plaintiffs' request for INDs for non-accused products, Defendant shall select three INDs that have molar ratios similar to the accused product and produce the Chemistry, Manufacturing, and Controls sections for each of those INDs. Following review of those documents, Plaintiffs may, if necessary, request additional INDs but only with a specific and detailed showing of need.
- 5. With respect to Plaintiffs' request for sales information about vaccines manufactured abroad and sold abroad, Plaintiffs shall propound to Defendant specific interrogatories about such sales that are narrowly-tailored to the factors enumerated in Halo Electronics, Inc. v. Pulse Electronics, Inc., 831 F.3d 1369 (Fed. Cir. 2016). After review of Defendant's responses, if Plaintiffs are able to demonstrate that a specific sale could be deemed a "U.S. Sale," they may renew their request for documents as to that sale.

6. With respect to Plaintiffs' request for Board of Directors' Minutes and Materials

Concerning the Accused Product, this request is **denied as moot** in light of the

parties' agreement on this issue.

7. With respect to Plaintiffs' request for litigation deposition transcripts of Moderna

witnesses from Moderna v. Pfizer, No. 22-cv-11378 (D. Mass) and Alnylam v.

Moderna, No. 22-cv-335 (D. Del.), Plaintiffs' request is denied as moot in light of

the parties' agreement on this issue.

**8.** With respect to Plaintiffs' request for documents from litigation in Moderna v.

Pfizer, No. 22-cv-11378 (D. Mass), Plaintiffs' request is denied as moot in light of

the parties' agreement on this issue.

**BY THE COURT:** 

/s/ Mitchell S. Goldberg

MITCHELL S. GOLDBERG, J.